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09/889,251 11/01/2001 Robert K. Naviaux UCSD1140-1 9760

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EXAMINER

KWON, BRIAN YONG S

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1614

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07/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



Art Unit: 1614

***Election/Restrictions***

***Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 67, 74-90, 111, 114-128 and 130-144 drawn to a method for a treatment of mitochondrial disorder comprising administering L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA.

Group II, claims 91 and 95-110, 129 and 145, drawn to reducing or eliminating one or more symptoms associated with a mitochondrial disorder comprising administering L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA.

The Inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in both groups is L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA. This element cannot be a special technical feature because the element is shown in the prior art (Page et al., Proc. Natl. Acad. Sci. USA, Vol. 94, pp. 11601-11606; JP 53056690; USP 6258795; North et al., Journal of Virology, 1981, p. 987-

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993; etc...). Therefore, Groups I and II do not share special technical feature with one another.

As such, unity between the above Groups I and II is broken.

### *Species Election*

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If applicant elects Group I or II invention, applicant is required under 35 USC 121 to elect a single disclosed species from following (a) or (b).

- (a). L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA mono-therapy.
- (b). L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA combination therapy with co-factors, vitamins or mixtures thereof.

If applicant selects Group I(a) or II(a), one specific compound from generic chemical structure of the compound represented by formula (I) or (IA), for example triacetyluridine, should be selected to be fully responsive.

If applicant selects Group I(b) or II(b), one specific compound from generic chemical structure of the compound represented by formula (I) or (IA) and "o-factors, vitamins, or mixtures of two more thereof", for example triacetyluridine and thiamine (B1) combination, should be selected to be fully responsive.

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In addition, if applicant selects Group I, one specific species from different mitochondrial disorder, for example MARIAHS syndrome, should be selected to be fully responsive. The following is a list of different inflammatory disorders or diseases, e.g., multiple mitochondrial deletion syndrome, Leigh syndrome, 3-hydroxybutyric academia, pyruvate dehydrogenase deficiency, complex I deficiency, complex IV deficiency, MARIAHS syndrome....

In addition, if applicant selects Group II, one specific species from “one or more symptoms associated with a mitochondrial disorder” should be selected to be fully responsive.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian-Yong S. Kwon whose telephone number is 571-272-0581. The examiner can normally be reached on 9:00-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/

Primary Examiner, Art Unit 1614